

## REMARKS / ARGUMENTS

The Taxol and Taxotere trademarks used in the specification are designated as such by utilizing the ® symbol. This conforms with MPEP 608.01(v), Examiner note 1. Therefore, Applicants believe that it is not necessary to amend the specification.

The present claims are now limited to those combinations comprising epothilone B as the epothilone.

Claims 20, 22-23, 25, 27-28, 31-35, 37, 44-45 and 50 were rejected under 35 USC 102(b) as anticipated by Vite et al. Since the current claims are limited to combinations wherein the epothilone is epothilone B, Applicants believe this rejection is overcome. Therefore, Applicants request reconsideration and withdrawal of this rejection with respect to the newly submitted claims.

Claims 20, 22-23, 25-27, 32-38, 40-42, 44-45 and 50 were rejected under 35 USC 102(e) as anticipated by Danishefsky et al. However, the paragraphs cited by the Examiner do not disclose any combination comprising epothilone B or specify that epothilone B should be used in a combination. Therefore, it does not identically disclose the presently claimed invention. For this reason, Applicants request reconsideration and withdrawal of this rejection with respect to the newly submitted claims.

Claims 20, 22-28, 30-42, 44-45 and 50 were rejected under 35 USC 102(e) as anticipated by Lee et al. Applicants point out that the reference's compound I is not epothilone B because the equivalent of the present A substituent is not O, as in epothilone B, but instead is -NH. Although the reference discloses that its compounds can be used in combination with other therapeutic agents, Applicants see no disclosure of a combination that includes epothilone B as the epothilone. Therefore, Lee et al does not identically disclose the presently claimed invention. For this reason, Applicants request reconsideration and withdrawal of this rejection with respect to the newly submitted claims.

There are three separate rejections under 35 USC 103(a): claims 21 and 29 over Lee et al in view of the Herceptin package insert, claims 21, 26, 29-30, 36 and 42 over Vite et al in view of the Herceptin package, and claims 24 and 38-31 (sic 41?) over Vite et al in view of Dixon et

al. Applicants request reconsideration and withdrawal of these rejections for the reasons that follow.

As noted above, compound I of Lee et al is not epothilone B. Lee et al's disclosure relating to combinations of therapeutic agents is limited to the epothilone derivatives disclosed therein, which Applicants believe does not include epothilone B. Therefore, while this reference combined with the Herceptin package insert may suggest therapy which combines Lee et al's derivatives with a HER-1 or HER-2 antibody, it does not make a similar suggestion with respect to the presently claimed combination wherein the epothilone is limited to epothilone B. Therefore, Applicants assert that claims 21 and 29 are not properly rejected over Lee et al in view of the Herceptin package insert.

Likewise, Vite et al 's disclosure relating to combination therapy is concerned with combinations that utilize its derivatives and does not suggest anything with respect to utilizing epothilone B in combination with other therapeutic agents. Applicants recognize that the reference discloses the chemical structure of epothilone B at page 1, but assert that its disclosure with respect to epothilone B is limited to indicating that it has a microtubule stabilizing effect similar to Taxol. It does not make any teaching or suggestion to utilize epothilone B in combination with other therapeutic agents. Therefore, Applicants assert that claims 21, 26, 29-30, 36 and 42 are not properly rejected over Vite et al in view of the Herceptin package.

Dixon et al is relied on as disclosing letrozole, an aromatase inhibitor. However, this disclosure does not overcome the deficiencies of the primary reference discussed above. Therefore, Applicants assert that claims 24 and 38-31 (sic 41?) are not properly rejected over Vite et al in view of Dixon et al.

For the reasons discussed above, Applicants request withdrawal of each of the rejections under 35 USC 103(a).

Claims 20, 26-27, 32, 36-37, 42, 44-45 and 50 were provisionally rejected for nonstatutory obviousness-type double patenting over claims 18-21, 23 and 26 of Application No. 10/469,367 in view of Hoffman et al, and claims 20, 23, 26-27, 32, 34, 36-34 (sic), 42, 44-45 and 50 were provisionally rejected for nonstatutory obviousness-type double patenting over claims 11-14 and 18-19 of copending Application No. 11/451,286 as evidenced by Hande. Applicants note that


each of the provisional rejections can be overcome, if appropriate, by a terminal disclaimer once claims are allowed.

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

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